K113133

DEC 15 2011

Section 5 – 510(k) Summary

Submitter: MEDRAD, INC.
One Medrad Drive
Indianola, PA 15051

Contact Person: Mike Burnside
Manager, Regulatory Affairs
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Date Prepared: December 15, 2011

Trade Name: MEDRAD Mark 7 Arterion Injection System

Classification: 870.1650

Product Code: DXT

Predicate Device(s): The subject device is equivalent to the following devices:

- K112086 Mark 7Arteion Injector System

Device Description: The MEDRAD Arterion Mark 7 is a software controlled medical device used to inject contrast agents from a 150ml disposable syringe. Commonly referred to as a powered injector it is designed to allow a user to fill a disposable syringe, and perform an injection with a preprogrammed volume and flow rate. The Arterion consists of three basic components or modules: a Power Unit, Display Control Unit (DCU), and an injector head.

Intended Use: The MEDRAD Mark 7 Arterion Injection System is intended to be used specifically for the purposes of injecting contrast medium and common flushing solutions into humans for angiographic studies.

Comparison to predicate: Design changes were made to the predicate device which included: adding a plastic seal that snaps on to the pressure jacket, adding a clear plastic cover designed to fit onto the drop front cone, and software modifications.

Performance Data: Bench and laboratory testing was performed to support a determination of substantial equivalence to the predicate device.
Results from the testing provide assurance that the proposed device conforms to the requirements for its intended use. This included the following testing:

- Pressure Jacket Pressure Cycle
- Pressure Jacket Syringe Insert/Remove Cycle
- Syringe High Pressure Life Use Case
- Disposables General Use Case
- Drop Front Engage/Disengage Cycle Test
- General Use Case Verification
- Software Verification/Validation

Conclusion: MEDRAD considers the Mark 7 Arterion Injection System to be substantially equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in functional design, materials, indication for use, fundamental technology, and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 19 2012

Medrad, Inc.
c/o Mr. Mike Burnside
Manager, Regulatory Affairs
One Medrad Drive
Indianola, PA 15051

Re: K113133
Trade/Device Name: Mark 7 Arterion™ Injection System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: II (two)
Product Code: DXT
Dated: November 29, 2011
Received: November 30, 2011

Dear Mr. Burnside:

This letter corrects our substantially equivalent letter of December 15, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113133

Device Name: MEDRAD Mark 7 Arterion™ Injection System

Indications for Use:

The MEDRAD Mark 7 Arterion Injection System is intended to be used specifically for the purposes of injecting contrast medium and common flushing solutions into humans for angiographic studies.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113133